DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 29, 2015

OSUNG MND CO., LTD
c/o Mr. Kiran Sheikh
Brite Sources USA
180 S. Western Avenue, #205
Carpentersville, IL 60110

Re: K141854
Trade/Device Name: Instrument Cassette (EFCCL1-F)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: September 11, 2015
Received: September 15, 2015

Dear Mr. Sheikh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141854

Device Name

Instrument Cassette (EFCCL1-F)

Indications for Use *(Describe)*

OSUNG INSTRUMENT CASSETTE (EFCCL1-F) is intended to hold instruments and accessories during storage and steam sterilization. This case cassette is intended to be used with a sterilized wrap in order to maintain sterility.
This case cassette is intended to be used with an FDA cleared sterilization wrap in order to maintain sterility.

Validated sterilization parameters:

Cycle Type	Temperature	Exposure Time	Dry Time
Gravity Steam	132℃ (270°F)	15 minutes	30 minutes

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 29 October, 2015

1. **Applicant/submitter:**

Manufacturer Name:	OSUNG MND Co.,Ltd. 57, Hwangguem-ro, 109beon-gil, Yangchon-eup, Gimpo-si, Gyeonggi-do, Republic of Korea Tel: +82-31-987-5395 Fax: +82-31-987-5397 E-mail:qa@osung.co.kr Establishment registration number: 9616119 Contact name: Taerim Lee

2. **Submission Correspondent**

Correspondent Name:	Kiran Sheikh Official correspondent: Brite Sources USA 180 S. Western Avenue, #205 Carpentersville, IL 60118 Tel: 312-895-1773 Fax: 847-589-1298 E-mail:support@britesourcs.com

3. **Device Name and Classification**

Trade/Proprietary Name:	Instrument Cassette (EFCCL1-F)
Common Name:	Instrument Cassette
Classification Information:	General Hospital 21 CFR 880.6850 Class II KCT

4. **Predicated Device**

Miltex Thompson Cassettes(K101653) Miltex Inc.

5. **Device Description**

The OSUNG INSTRUMENT CASSETTE is designed to handle reusable dental instruments for sterilization and storage. This device is intended to hold instruments and accessories during storage and steam sterilization, and to be used with a sterilized wrap in order to maintain sterility.

The OSUNG INSTRUMENT CASSETTE is comprised of a base, lid, silicone mat/rail, holders, and spring lock system.

The internal insert cassette has the ability to hold individualized pieces and accessories which include scissors, needle, elevators, forceps, pincers, retractors, mallets etc.

Description and Dimensions

Model No	Description	Max no of instruments	Dimensions (mm) [L X W X H]	Max Weight (with instruments)	Total Surface area (mm^2)	Perforation (%)	Silicone Surface area (mm^2)
EFCCL1-F	Perforated lid & bottom, Mid length instruments & tools(forceps, elevators)	10	205 X 305 X 31	1,302.0	150,118	29.0	71,622

6. Intended Uses

OSUNG INSTRUMENT CASSETTE is intended to hold instruments and accessories during storage and steam sterilization. This case cassette is intended to be used with a sterilized wrap in order to maintain sterility.

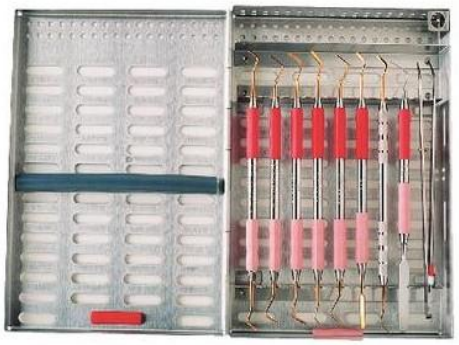
This case cassette is intended to be used with an FDA cleared sterilization wrap in order to maintain sterility.

Validated sterilization parameters:

Cycle Type	Temperature	Exposure Time	Dry Time
Gravity Steam	132℃ (270°F)	15 minutes	30 minutes

7. Substantial Equivalence

The Table below shows that the substantial equivalence through side-by-side comparisons between the OSUNG Instrument Cassette and predicate device of Miltex Thompson Cassettes (K101653). The comparison analysis consists of the products' intended use, technological characteristics and performance testing to support the substantial equivalency to its corresponding predicate devices.

Subject device	INSTRUMENT CASSETTE(EFCCL1-F)	Miltex Thompson Cassettes
510(k) Number	new	K101653
Manufacturer	OSUNG MND Co.,Ltd.	Miltex Inc.
Indication for use	OSUNG INSTRUMENT CASSETTE is intended to hold instruments and accessories during storage and steam sterilization. This case cassette is intended to be used with a sterilized wrap in order to maintain sterility. This case cassette is intended to be used with an FDA cleared sterilization wrap in order to maintain sterility.	Miltex Thompson Cassettes are general dented/surgical instrument cassettes indicated to hold instruments and accessories in place during storage and the sterilization cycle. Suitable for Gravity Steam and Pre-Vacuum Steam, the cassettes are intended to be used in conjunction with sterilization wrap in order to maintain sterility.
Shape		

Dimensions(LXWXH)	Model No	Dimensions(mm)	Model No	Dimensions(mm, inch)
	EFCCL1-F	205 X 305 X 31	3-083005	204X81X30
			3-083105	204X81X30
			3-083210	204X81X30
			3-084007	204X124X28.5
			3-084107	204X124X28.5
			3-084214	204X124X28.5
			3-085009	204X154X30
			3-085109	204X154X30
			3-085218	204X154X30
			3-089110	204X229X28.5
			3-118114	204X276.5X30
			3-118116	204X276.5X30
			3-118122	204X276.5X30
			3-139126	232X330X30
			3-072007	178X67X17
			3-082008	203X127X17
			STDSL27	178X67X25
			3-072014	178X115X17
			STD222	204X276.5X30
			STD209	-
			STDSTAT	178X270X38
			STDSTAT8	171X206X29
			STDSTAT814	171X206X29
			STDORTHO	127X178X51
			STDBOS	178X76X35
			STDBOM	254X140X102
			3-080205	204X71X37
			4-6835	6-1/2 x 6-1/4 x 1-3/16(inch)
			4-083000	8 x 3-13/16 x 1-3/16(inch)
			4-084000	8 x 4-7/8 x 1-3/16(inch)
			4-085000	8 x6 x 1-3/16(inch)
			4-089100	8 x9 x 1-3/16(inch)
			4-008122	8 x11 x 1-3/16(inch)
			4-008115	8 x11x 2(inch)
			4-009126	9-1/8 x13 x 1-3/16(inch)
			4-6815	15 x8-1/4x 1-3/16(inch)
			STDBH	-
			STDBH6	-
			STDBHS	-
			STDBB2	
			STDPB	42X33X26
			STDES48	-
			STDES60	-
			STDES72	
Raw materials	Stainless Steel Silicone		Stainless Steel Silicone	

Maximum number of instruments

Model No	Max no. of Instrument
EFCCL1-F	10

Model No	Max no. of Instrument
3-083005	5
3-083105	5
3-083210	5
3-084007	7
3-084107	7
3-084214	7
3-085009	9
3-085109	9
3-085218	9
3-089110	10
3-118114	14
3-118116	16
3-118122	22
3-139126	26
3-072007	7
3-082008	7
STDSL27	7
3-072014	14
STD222	22
STD209	
STDSTAT	14
STDSTAT8	8
STDSTAT814	14
STDORTHO	-
STDBOS	-
STDBOM	-
3-080205	-
4-6835	
4-083000	
4-084000	
4-085000	
4-089100	
4-008122	
4-008115	
4-009126	
4-6815	
STDBH	-
STDBH6	-
STDBHS	-
STDBB2	-
STDPB	-
STDES48	-
STDES60	-
STDES72	

Maximum weight

Model No	Weight of each cassette with instruments(g)
EFCCL1-F	1,302.0

Not stated in summary

Sterilization method	**Gravity steam:** ExposureTime:15 minutes Temperature: 132 °C Drying: 30 minutes.	**Gravity steam:** ExposureTime:30 minutes Temperature: 121°C Drying: 20 minutes. **Pre-Vacuum steam:** ExposureTime:4 minutes Temperature: 132 °C Drying: 20 minutes.
Reusable	**Yes**	**Yes**

8. Performance data

Validation test for steam sterilization, validation of ultrasonic cleaning and limit of reuse test for the OSUNG INSTRUMENT CASSETTE(EFCCL1-F) has been carried out as the results were shown by test reports.

All of tests demonstrated compliance to both safety and effectiveness requirements that apply to the device, in terms of sterilization performance, maintenance of sterility and reusability.

Hence, the OSUNG INSTRUMENT CASSETTE(EFCCL1-F) demonstrated appropriate performance that is substantially equivalent to the predicate device and that the design output meets the design input requirements.

Performance Test	**Standard(s) used**	**Results**
Half cycle sterilization validation at 132°C	ISO 17665-1(2006) ISO 17665-2(2009) ANSI/AAMI ST79(2010) & A1(2010) & A2(2011) & A3(2012) & A4(2013)	No growth at half cycle. (Pass)
Dry Time Validation		The minimum weight difference was -0.05% (Pass)
Cleaning Validation	AAMI TIR 30 (2011)	Below the limit of detection for protein and hemoglobin after ultrasonic cleaning.
Limits of Reuse	FDA Guideline: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (2011) AAMI TIR12(2010) AAMI TIR30(2011)	Performed 100 reuse cycles

9. Conclusions

Based on the intended use, indications for use, technological characteristics, and performance data, the Instrument Cassette is substantially equivalent to the Miltex Thompson Cassettes (K101653).

Following consideration of all information presented to support substantial equivalence of the Instrument Cassette to the predicate device, similarities in intended use, design, principles of operation, and performance specifications were identified. The performance data following validation tests carried out for the Instrument Cassette showed that it is substantially equivalent to the known performance of the predicate device, Miltex Thompson Cassettes